

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff and Counterclaim Defendant,	)	
	)	
v.	)	C.A. No. 07-229 (GMS)
	)	
RANBAXY INC., and RANBAXY	)	
LABORATORIES LIMITED,	)	
	)	
Defendants and Counterclaim Plaintiffs.	)	
	)	

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**JOINT MOTION FOR EARLY SCHEDULING CONFERENCE**

The parties, Merck & Co., Inc. (“Merck”) and Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively “Ranbaxy”), hereby jointly request an early scheduling conference.

Merck brought this lawsuit for patent infringement in response to an Abbreviated New Drug Application (“ANDA”) filed by Ranbaxy with the FDA. Ranbaxy’s ANDA seeks approval to manufacture and sell a generic version of the Merck drug PRIMAXIN®, which is an antibiotic used to treat bacterial infections. PRIMAXIN® contains a combination of the antibiotic imipenem and the enzyme-inhibitor cilastatin, which prevents imipenem from being broken down by the body.

This case differs from most ANDA litigations because PRIMAXIN® is an antibiotic which was considered for approval by the FDA before 1997. As the Court is aware, in most ANDA litigation, the filing of the complaint automatically stays FDA approval for thirty months. 21 U.S.C. § 355(c)(3)(C). The automatic thirty-month stay does not apply, however, when the ANDA is directed to an antibiotic which was considered for approval before November 1997, such as PRIMAXIN®. 21 U.S.C. § 355(j)(5)(B)(iii); *Allergan, Inc. v. Crawford*, 398

F.Supp. 2d 13, 17-18 (D.D.C. 2005). Thus, here, the FDA can give final approval (not just tentative approval) for Ranbaxy to begin marketing its ANDA product when the FDA has completed its review of Ranbaxy's application, even if the litigation is still ongoing.

The parties respectfully request that the Court set a scheduling conference as early as would be convenient for the Court. The parties have now completed the filing of their pleadings: Merck filed its Complaint on April 30, 2007, Ranbaxy filed its Answer and Counterclaims on June 21, 2007, and Merck filed its Reply to Ranbaxy's Answer and Counterclaims on July 11, 2007.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Mary B. Graham*

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